REMARKS/ARGUMENTS

General

The pleated stent assembly as disclosed in the present application and claimed in this Amendment has numerous unique physical features, which provide singularly and in combination, useful and unprecedented results, as compared to the prior art in these challenging medical fields. The pleated stent assembly of the present invention is designed and manufactured primarily for use in endovascular treatments, specifically neuroradiology. This field has very unique, rigorous, and exacting standards for medical devices. In this area of medical practice, it is often challenging to deliver a device to the treatment site and it is very easy to cause further damage to fragile arteries when delivering and deploying a medical device. Applicants' preferred embodiment establishes functionality of the invention in the most demanding of interventional fields, where delivery crossing profile dimensions, delivery flexibility, and deployment control, are crucial. Applicants' invention provides a useful solution to a felt need by significantly increasing the percent of lumen sites that can be accessed and treated interventionally (i.e. without open surgery). This invention is a huge improvement over coiling, the ONLY FDA approved, non-surgical aneurysm treatment. A pleated stent assembly of this invention provides an unprecedented and useful tubular medical device, which gently and precisely conforms to irregular lumen geometry, while providing a strong and self supported lumen treatment.

Neuroradiology is the most challenging and demanding of any interventional field in terms of device delivery parameters and suitability of physical features affecting deployment characteristics. The distal arteries of the brain become increasingly small and tortuous. Many conditions, such as aneurysms, needing treatment are found on tortuously shaped arteries smaller than 2 mm in diameter. Applicants' invention, unlike any referenced prior art, has chosen interventional treatment of neurological aneurysms as a preferred embodiment. None of the prior art cited by Examiner is designed, intended, suggested, or implied for neurovascular use. No cited prior art EVER MENTIONNS neurovascular use. No cited prior art is analogous art. All cited references are out of date in this rapidly changing field and if it had been obvious or

even possible to modify or combine existing art to create a workable neurovascular aneurysm cover stent, the felt need to have a better solution than coiling or open surgery would have been proposed and developed. Due to the physical differences between applicants' invention as claimed and the cited references, none of the prior art is capable of safe or effective use in interventional neuroradiology. Given the demand for better non-surgical aneurysm and perforated lumen treatments, applicants' invention usefully meets a felt need in these most serious of medical fields. Applicants' invention is disclosed in full and clear detail, based on extensive prototype testing and development, giving exact parameters that allow anyone skilled in the art to understand and replicate the invention (please see Exhibits A-B on enclosed CD).

Claims 1-21 are pending. Claims 22-31 have been cancelled without intending to abandon or to dedicate to the public any patentable subject matter. In the Remarks section of this Amendment, applicant has clarified the physical features and properties of the present invention and referenced discussion of these physical traits in the specification and amended claims to elucidate the usefulness, novelty, and non-obviousness of applicants' pleated stent assembly. As set forth more fully below, reconsideration and withdrawal of the Examiner's rejections of the claims are respectfully requested.

Species Election

Applicant elects for examination, without traverse, the PLEATED STENT ASSEMBLY disclosed in the specification filed October 28, 2003 and recited by Claims 1-21. Claims 1-21 are currently pending.

Information Disclosure Statement

Point 12 has been addressed. In regard to Point 11, it is unclear if there is anything else wrong with the submitted Information Disclosure Statements. The Office Action does not point out any deficiency. Clarification is requested.

Claim Rejections Under § 102 Overcome

General Response: The present invention, as claimed and described in the specification, contains numerous novel physical features and characteristics which differ significantly from those found in the prior art or any combination thereof. These novel physical characteristics

provide useful benefits for the less invasive treatment of neurovascular aneurysms among numerous other difficult to treat conditions. Such benefits include a relatively small crossing profile for delivery, increased flexibility during delivery, slow and controlled deployment, high surface area density after deployment, very low pressure deployment, less risky deployment, smooth generally cylindrical inner surface after deployment, exact contouring to non-uniform artery shapes, low pressure inflation, ductile material, and strong yet thin material (won't break, crack, or tear).

It is important to note that there are *no* balloon expandable neurovascular stents in use or in the prior art! This is because before applicant, no one had figured out how to get a balloon stent assembly to be flexible and small enough to make use in the brain feasible.

The current application discloses a thin, ductile pleated stent capable of being plastically deformed in any direction, without kinking or wrinkling, due to novel physical features including inventive stent wall pattern and manufactured material properties. The pleated stent of the present invention provides an ideal solution to the felt need in the art for a vascular repair implant capable of delivery deep into tiny, tortuous, and extremely fragile anatomy, with low risk of failure or inflicting additional damage to arteries or aneurysms.

In regard to examiners Point 16-17, Boussignac does not anticipate Claims 1-3, 5, or 18.

The Examiner has rejected Claims 1-3, 5, and 18 under 35 U.S.C. § 102(b) as being anticipated by Boussignac (U.S. Pat. No. 6,056,767). The Examiner states that Boussignac, and specifically Figures 1, 2, 7 and cited specification text teach each of the limitations of Claim 1-3, 5, and 18 of the present application, as filed. Applicant respectfully traverses this rejection. Claim 18 has been cancelled.

Presently amended Claim 1 recites a "tube... wherein the wall of said tube is comprised of a pattern of interconnected solid area defining open spaces therebetween, and wherein said solid area is continuous".

Boussignac does not teach a tube. The spiraled wire (2, Fig. 1) is not a tube. Pleating a tube is much different than pleating a wire. Applicants' tube has unprecedented thinness and pleatability. Boussignac is designed as a support stent for a lumen that would otherwise shrink

or collapse (at least Abstract, col. 2 lines 42-44). Boussignac mentions aneurysm treatment as an afterthought (col. 5 lines 28-9). There is zero discussion in the Boussignac specification about how the proposed device could be used to treat aneurysms. The aneurysms contemplated for treatment could only be non-neurovascular aneurysms which are more easily accessed. Boussignac could only block flow into an aneurysm if the framework were covered. Boussignac mentions a cover for its spiraled wire frame (col. 4 lines 26-30). This is a concept far different and inferior to applicants' one piece, continuous, one material, biocompatible, easily endothelized device. No covered stent has ever been made capable of neurovascular delivery except by applicant (Exhibit A and B). This is due to the inability of a device like Boussignac to be delivered into the brain, much less to reach the distal aneurysms beyond the carotid siphon, which only applicant can reach. Applicant provides a one piece, continuous, aneurysm cover with numerous novel physical features not taught by Boussignac.

Claim 1 has been amended to incorporate the material of claim 10 describing patterning. Claim 1 has been also amended to specify that the material composing the "solid area" of the "tube" is "continuous." This continuity is in contrast to overlapping wires or wire and cover used by Boussignac. Boussignac illustrates only a spiraled wire and provides NO discussion about how said wire could seal the neck of an aneurysm, unless a cover is used, and even then Boussignac never mentions covering a defect. Pleating a wire as small as needed to access the brain anatomy is not taught at all by Boussignac. Pleating a wire is far different in features and functionality from the pleated, thin, ductile, wall of applicants' continuous tube. Applicant discloses in full and clear detail how to pleat such a tube with appropriate size parameters for neurovascular delivery (at least pars. 51-55). Boussignac does not teach several of the limitations presented in Claim 1 from which all other pending claims depend.

Claim 2 recites "The device of claim 1, wherein said tube is formed from a material that undergoes sufficient plastic deformation along said pleating lines to substantially maintain said delivery width of said tube/balloon assembly." Claim 2 is a fortiori patentable as it depends from claim 1. Additionally, the tube is formed from "a" material as opposed to multiple combined materials. The plastic deformation along pleating lines taught by applicant is

presented in clear detail giving sizing and thickness parameters sufficient for neurovascular delivery (at least pars. 19, 32, and 33).

Applicants' device achieves an unprecedented result in the field, in that once deployed the stent is in the shape of the treated lumen, even if the lumen is irregular, and even if the shape of the lumen is different from the manufactured shape of the tube. This provides at least better sealing over the aneurysm and allows the device to be grown into the artery wall. Boussignac does not allow this beneficial feature, as it is a spiraled wire it cannot stretch. If the spiral did expand, the length of the stent would have to shorten, which is unacceptable in defect cover placement. Boussignac is limited to being sized correctly in advance to fit the artery in its manufactured shape (col. 2 lines 55-58, col. 3 lines 10-11, col. 4 lines 23-24). A smooth internal deployed stent surface is required to prevent clotting in nearly all cardiovascular and neurovascular cases. Applicants' invention may be deployed to conform to non-uniform arteries, and even in these cases, due to the unprecidentedly thin, strong, and ductile wall, as the device has unique plastic deformation capabilities, the interior lumen of the deployed stent will be contoured tightly to the natural shape of the artery wall. Thus the deployed pleated stent shape will be smooth without pleats, wrinkles, folds, or perforations. In the medical specialties to which applicants' invention is directed, any device inner diameter irregularities or protrusions into the artery lumen will create significant risk of potentially fatal clot formation. The relative thinness of this invention provides numerous benefits (at least Pars. 33 and 59).

Unprecedented material and design properties of the present invention insure the useful result that the internal expanding means will push any protruding stent portions tightly against the artery wall, with out spring back, by virtue of the low pressure plastic deformability of the stent.

The preferred embodiment of applicants' invention discloses a method to repair, essentially patch, a hole or other defect in a body organ with no objective or requirement to be thick enough or strong enough to provide structural support to an artery which would otherwise tend to collapse. Bouissignac is intended to support a lumen in all presented embodiements (at least Abstract, col. 2 lines 42-44) and thus must have much different design features than those

taught by applicant. Due to design and use requirements, the present invention needs less material mass, and less material strength, to function as intended which enables the valuable result of a smaller possible cross section and increased flexibility for delivery. Another distinct advantage provided by the unique physical features of the present invention, the ability to use a low pressure compliant balloon or other low pressure expanding means, also contributes to small delivery diameter and flexibility of the invention.

The stents of the present invention are unique in their ductility, which facilitates pleating on an exceptionally thin tube with an exceptionally small diameter. Additionally, the thin, uniform, and ductile stent wall is highly advantageous for accomplishment of the unprecedented result of currently amended Claim 1 which describes a tube capable of neurovascular use.

Applicants' patented stent electroforming techniques and related know-how, combined with the novel physical features of the Claim 1of this invention provide the unique result of enabling pleating of longitudinal pleats, which are symmetrical and uniform, into a tube with an original diameter as small as 2 mm. The thin wall material of the present invention is unusually strong in its deployed cylindrical shape and extremely flexible in its compacted delivery state. A woven, braided or spiraled wire design will need to be much thicker in order to have the same structural effectiveness and patching ability as applicants' invention. These characteristics of a pleated stent enable the unprecedented efficacy of the smaller, more flexible, and safer, delivery assembly of the present invention. Applicants' specification discloses in clear and complete detail how to build and use the invention, of which prototypes have been deployed successfully deep into animal brains (see Exhibits A, B, and C). In this crowded art, Boussignac does not teach each of the limitations of applicants' Claim 1.

Applicant therefore respectfully requests that the Examiner's rejection of Claim1 and all dependent Claims under 35 U.S.C. § 102(b) be withdrawn.

A significant advantage of the device of the present invention is that the stent can be deployed with its wall permanently(no spring back) conforming exactly to the geometry of the lumen, into which the device is deployed, rather than forcing conformation of the body lumen to the stent or leaving gaps between the stent and the lumen. A spiraled or otherwise shaped wire

design of Boussignac cannot locally stretch and conform to vessel irregularities as can applicants' thin walled tube with novel patterning and material properties. Boussignac will force the artery to conform to the stent which is very dangerous around aneurysms where the tissue is fragile. The novel features taught by the present disclosure and not taught by Boussignac, provide numerous results which make the device safer, more effective, and realistically usable to treat many lumen defects which a doctor would never use a device of Boussignac to treat.

The use of a compliant balloon or other low pressure expanding means is unprecedented in the prior art in the fields of stent inflation. Currently used, and proposed, balloon expandable stents need much higher pressures to inflate or seat against the artery, in which case an elastic balloon would blow out at the ends of the stent before inflation was accomplished. These stents are slightly ductile at high pressures, where a pleated stent of this invention is many times more ductile at many times less pressure. The pressure needed to inflate and permanently seat a device of the preferred embodiment of the present invention is about .5atm to 3 atm (par. 59, par. 60 last sentence) where the typical pressure needed to deploy current balloon expandable stents is over 12 atm. There is demand among the interventionalists using the products for lower pressure devices, for among other reasons they create less danger.

In regard to Claim 3, Boussignac is never self expanding and thus would not need a restraining sleeve. Claim 3 recites "The device of claim 1, further comprising a tubular sleeve substantially surrounding said tube/balloon assembly to substantially maintain said delivery width of said tube/balloon assembly". The "cover" (col 4 line 26) of Boussignac is an attempt to accomplish what applicant ALONE accomplishes with a one piece, continuous, thin walled tube. A stent framework covered with something else (col 4 lines 26-30) does not teach any of the limitations of Claim 3. In Claim 3 and 4 Applicant recites the only pleated, thin walled, self expanding stent. In Column 4 lines 39-40 Boussignac merely teaches dunking or otherwise coating the wire framework with another material to fill in the holes. Here again applicant accomplishes this goal more effectively with a *one piece*, *one material*, exceptionally thin, strong, and ductile tube which can be manufactured and patterned to provide the density needed to cure an aneurysm or other defect.

In regard to Claim 5, Boussignac never mentions longitudinal flexibility and Figures 1 or 2 do not teach longitudinal flexibility, they merely show a wire wrapped in a circumferential spiral around a cylinder. Please see Exhibit A showing longitudinal flexibility of the present invention. Claim 5 is a fortiori patentable as it depends from claim 1.

The novel physical features of the present invention are significantly different from any disclosed in Boussignac, whereby several unique and valuable advantages are realized.

The patterns of holes described and claimed by applicant (pars. ??, and figs. ?), are specifically designed to facilitate both a flexible delivery assembly and plastic deformation of at least some of the solid areas of the pleated stent during deployment. These patterns and unique material properties provide at least two useful benefits. First, longitudinal and general flexibility during delivery prevents artery damage and facilitates delivery deeper into challenging anatomy. Second, the patterns and physical properties of applicants' invention allow customized, gentle, slow, and controlled expansion of the stent to fit perfectly to the body lumen. The present invention achieves these results without forcing the lumen to conform to the stent shape, and without the need to stretch (over-expand) the lumen and stent.

Additionally, these inventive patterns and the novel manufacturing process, which make such intricate patterning on the wall of such a small device possible, enable exact and gentle contouring of the pleated stent to the lumen wall, creating useful, unexpected, and unprecedented results.

Applicants' device achieves a solution to a much felt need due in part to its exceptional thinness, bio-compatibility, and consistent artery contact after deployment. As mentioned, the artery geometry around anticipated treatment sites, especially aneurysms, is usually irregular in diameter and shape. In the treatment of aneurysms the most likely cause of failure of the treatment is the recanalization, or reforming, of the aneurysm due to the high and pulsing pressure of blood. Assuming even slight gaps between the ends of the stent and the artery, it is clear to visualize a stent or other defect patch with blood flowing around it (i.e. between the stent and the lumen wall), and recannalizing a path to the defect. The features claimed and described by applicant, which are not taught, mentioned, or desired by Boussignac, allow solvency and

functionality unattainable by Boussignac.

Using disclosed techniques, these holes may be patterned on an unprecidentedly fine and precise scale into the very thin, pleated stent wall. Rapid and consistent endothelization is valuable in treatment of holes or defects in body lumens, and especially in aneurysm treatment, in order to prevent leakage of blood past the barrier the device provides. Additionally, once applicants' device is covered over by endothelial cells, clots will not form internal of the stent as is the current problem with drug eluting stents which are not endothelized.

Creating, folding, delivering, and deploying, a device in the 2-5mm diameter range, through challenging anatomy is something Boussignac does not discuss nor disclose even vague ideas on how to accomplish.

It is not possible for a device of Boussignac to be deployed at a diameter larger than the manufactured (original) diameter of the tube.

Additionally, applicant provides a balloon expandable lumen defect covering device which is one piece with no possibility of a patch or other portion separating or not being deployed in proper conjunction with an underlying stent or support structure (claims 1 and 2).

Applicant has built and tested multiple, actual scale prototypes, and is familiar with medical device requirements in the neurovascular field. Additionally applicant has been granted three patents allowing the manufacture of cylindrical electroformed stents, and applicants' research facility is uniquely positioned to make inventive steps not accessible to others in the field.

Claim Rejections Under § 103 Overcome

The Office Action (point 21) rejected Claims 1-14, 18, and 21 under 35 U.S.C. § 103 as being unpatentable over Drasler (US Pat. No. 6,287,335) in view of Boussignac (US Pat. No. 6.056.767). Claim 18 and 10 have been cancelled. The material of claim 10 has been included in amended claim 1.

Presently amended claim 1 recites, "A pleated stent assembly comprising: ...a tube...wherein the wall of said tube is comprised of a pattern of interconnected solid area defining open spaces therebetween, and wherein said solid area is continuous." In the

specification applicant discloses a ductile continuous tube, between .001 and .003 inches thick (par. 19, 33, 34), which never contains multiple materials, wires, woven fabric, hinges, or joints, as necessitated by Drassler and Boussignac or any combination thereof. The uniform and continuous nature of applicants' inventive tube provides numerous benefits including unprecedented functionality and biocompatibility (at least Pars. 19, 23, 25, 33, 34, 39, and 59). Pleating a thin walled tube as disclosed by applicant requires different techniques than those disclosed by Drassler. Applicant describes these pleating techniques in detail (at least pars. 51-55). This invention uses a relatively thin (par. 59) balloon to provide slow, gentle, and controlled expansion of the pleated stent at a maximum pressure far below the minimum pressure used to expand modern stents (at least par. 25 sentences 5-6, par. 52, par. 59) including lumen support stents like Drassler and Boussignac. Drassler only discloses plastic deformation of an imbedded wire during pleating (at least col. 8 lines 9-15 and 44-53, and never deformation of a nearly solid continuous tube as taught by the present invention. Drassler is intended for use in the abdomen and other lumen many times larger than those for which this invention is designed. Pleated grafts such as Drassler have existed for many years and none have ever been used in the brain and no such device is currently in the prior art. Numerous advantages ensue from the non-obvious physical differences between the tube of Claim 1, as discussed herein and above in response to Point 17 above, and the woven "tubular member" of Drassler. Unlike the present invention, the woven device of Drassler shortens longitudinally as it expands radially (col. 6 lines 31-35). Applicant also discloses the option that the whole tube can be expandable beyond its original diameter (par. 39).

Unlike applicants' stent which has virtually no spring back, Boussignac and Drassler would need much larger pressures and a stronger, thus larger, balloon to plastically deform the stent which is intended to support a lumen which would otherwise shrink or collapse (at least 12 Abstract, col. 2 lines 42-44). This causes the damage and associated undesirable tissue growth remedy with application of a drug. Applicant prevents this damage from ever occurring, by utilizing inventive features to accomplish precise artery contouring, with minimal over-inflation and with virtually no spring back, at much lower pressures than ever utilized for stent expansion.

The features of applicants' device, including a optionally nearly solid smooth cylinder that is pleated and then unpleated to a smooth generally cylindrical shape, combined with novel applicant patented manufacturing techniques, and device patterning, provide a relatively very thin device with great structural stability (at least par. 33 sentences 7-8). In the preferred embodiments of applicants' invention much less resistive strength at the deployed shape is needed than with support stents like Drassler and Boussignac. This enables applicant's device to be relatively very thin, thus further reducing delivery diameter, increasing delivery flexibility, allowing a lower pressure (smaller) balloon to be used, and avoiding damage to fragile lumens during delivery and deployment.

Typical balloon expandable coronary stents are made of stainless steel or Cobalt Chromium or similar alloys. These devices are somewhat ductile but many times less ductile than applicants, devices. These devices are slightly plastically deformed by an internal high pressure balloon, and they do have significant spring back, and thus the stent and lumen must be over expanded 10-20%, causing lumen response in the undesirable form of restenosis which can clog the artery. The features of the present invention enable avoidance of restenosis as never before possible with a balloon expandable stent. *Restenosis* is to be distinguished from *endothelization*, which applicant desires and uniquely facilitates by fine patterning, thinness, and bio-compatibility, thus facilitating rapid tissue in-growth through holes in the stent wall resulting in the stent being *endothelized* into the lumen wall (par. 24, 33, sentences 7-8, and 59). This is the ideal result in the fields to which the present invention is directed. *Restenosis* is a dangerous closing off of the treated artery, which applicant uniquely avoids. Due to the unprecedented and useful physical features of applicant's pleated stent, an elastic balloon or other low pressure expanding means may be used. This provides several useful results including a balloon with a relatively very small crossing profile in its resting state. Drassler does not intend or mention neurovascular use and therefore does not teach the several features of this invention which allow actual deployment and use in locations which are not possible with Drassler or Boussignac or any obvious combination thereof. The customized balloons disclosed by applicant, and used by applicant in prototypes, are designed to exert only .5-7 atm on the interior of the stent.

In regard to claim 2, which recite the tube of claim 1 "formed from a material" that is plastically deformed during pleating. Nitinol is elastic and not plastically deformable. The materials described by Drassler (Nitinol, Col. 8, lines 9-15) have a "high elastic modulus" which is the opposite of being plastically deformable as recited by Claim 2. Only applicant teaches a continuous tube that is plastically deformable. Claim 2 is also *a fortiori* patentable as it depends from claim 1.

Claim 3 is a fortiori patentable as it depends from claim 1.

Claim 4 describes a novel continuous tube which is pleated and self expandable. Woven strands of nitinol, like Drassler are well known in the art. Applicant discloses the first thin walled tube which contains no wires and can thus be made thinner and more effective for aneurysm treatment (par 63). Claim 4 is also *a fortiori* patentable as it depends from claim 1 and claim 3.

Claim 5 recites said "tube" of claim 1 with "pattern of interconnected solid areas" additionally "flexible along its longitudinal axis." Examiners citation to (Col. 6 lines 31-35) is apparently in error. The features of applicants' tubular stent enable longitudinal flexibility due to novel wall properties and thinness and due to the ability to use a relatively thin balloon (at least 25 sentence 5-6, 52, and 59). Making a large artery (AAA) stent like Drassler into a neurovascular stent requires many changes in physical features not simple sizing changes. Applicant alone teaches the non-obvious steps to create and deploy the only neurovascular and hard to reach defect nearly solid wall tube. Claim 5 is also *a fortiori* patentable as it depends from claim 1.

Claim 6 describes a unique solid or nearly solid body section. Drassler Fig. 23 does not teach or suggest such a solid body section. A woven section is different than that disclosed by applicant as discussed above. Claim 6 is also *a fortiori* patentable as it depends from claim 1.

Claim 7 is *a fortiori* patentable as it depends from claim 1. Additionally, a pleatable solid body section suitable for small and tortuous vessels is disclosed only by applicant.

Claim 8 discloses a part of the continuous thin walled tube which is expandable beyond its manufactured diameter. Making a thin walled tube able to stretch (plastically deform) is far

different from and not made obvious by the deforming hinges of Drassler. The Drassler disclosure necessitates at least two different materials. As explained above and in the specification one ductile material used to construct the WHOLE tube is more effective and biocompatible and useful than the "hinged" anchor sections of Drassler. Claim 8 is also *a fortiori* patentable as it depends from claim 1.

In regard to Claim 9 please see response regarding claims 1 and 8 above. Claim 9 is also *a fortiori* patentable as it depends from claim 1 and 7.

In regard to Claim 10, this material has been incorporated into claim 1. Drassler does not teach or suggest the type of interconnectedness described by applicant. The continuous solid areas of this invention are different than woven wires of Drassler.

Claim 11-14 are at least *a fortiori* patentable as they depend from claim 1.

Claim 21 is a fortiori patentable as it depends from claim 1. The "biocompatible plastic" of claim 21 would have to function as required by claim one which is not taught or made obvious by Drassler in view of Boussignac.

The Office Action (point 22) rejected Claims 15-17 under 35 U.S.C. § 103 as being unpatentable over Drasler (US Pat. No. 6,287,335) in view of Boussignac (US Pat. No. 6.056.767) and furthering view of Penn (US Pat. No. 6,375,667.

Presently amended claim 15 recites "The device of claim 1, wherein said solid areas are comprised of longitudinal struts and interconnected circumferential struts." Claim 16 recites "The device of claim 15, wherein said wall comprises at least one annular anchor section, wherein the circumferential struts in said anchor section are radially expandable beyond said original diameter." Claim 17 recites "The device of claim 16, wherein said wall comprises at least one annular body section, wherein the circumferential struts in said body section of said wall are radially non-expandable substantially beyond said original diameter". Claims 15-17 are *a fortiori* patentable as they depend from claim 1. Several features recited by these dependent claims are not obvious from the Penn disclosure in view of Drassler and Boussignac. By inventing a tubular stent with all the features encompassed in Claim 15-17 applicant has achieved solutions to several long felt needs in these fields, none of which would be obvious, to

one skilled in the art, from the disclosure of Penn in view of Drassler and Boussignac.

Applicants' specification centers on the needs met, and benefits provided by, a ductile pleated stent which can be expanded, optionally, in some or all portions, beyond its manufactured diameter, by a relatively very low pressure internal expanding means (Pars. 18, 20, 21, 23, and 31). Applicants' balloon expandable pleated stent can accomplish the delivery of a nearly solid surface area stent, to a remote lumen defect, even when deployment requires expansion of some or all of the stent to 50% beyond manufactured diameter. It is noted that this is much less expansion than that needed by a purely radially expandable stent like Penn, which need to expand 300-400 %. The unique features of the patterning of claims 15-17 applied to the thin walled, ductile tube, which can be pleated down to minimize necessary expansion and thereby facilitate delivery of a one piece, high surface density defect cover of the present invention (at least par. 20-23, and 25), are not made obvious by Penn in view of Drassler and Boussignac.

Applicant respectfully traverses Examiners suggestion that the material of Claims 15-17 is made obvious by the Penn disclosure in view of Drassler and Boussignac.

The Office Action (Point 23) rejected Claim 19 and 20 under 35 U.S.C. § 103 as being unpatentable over Boussignac in view of Hines (US Pat No. 6,019,784).

In regards to examiners Point 23, Claim 19 recites a "device of claim 18, wherein said tube is formed from an electroformed metal." Claim 20 recites, "The device of claim 19, wherein said metal is gold." Both claims 19 and 20 are *a fortiori* patentable as they depend from claim 1. Hines (US Pat. No. 6,019,784) does not teach a thin walled, pleatable tube as disclosed by the present invention. Cited portions of that disclosure describe a "stent" not a tube as disclosed by applicant in the present invention. The stent disclosed by Hines is not meant to be pleated but to be radially expanded like typical balloon expandable stents, thus it has numerous different physical features. Hines teaches a *support* stent to hold open a lumen, like Boussignac, which needs to have very different material and design parameters than the aneurysm/defect covering stent of the present invention. The ability to create and utilize a much thinner wall provides numerous advantages (at least par. 19, par. 33 sentences 7-8, and par. 38).

Due to radically different device uses, desired functionality, and design parameters the disclosure of Hines does not teach or make obvious in view of Boussignac, the teachings of Claim 19, or 20. The disclosure of Hines does not teach the relatively much more solid wall of the present invention or the relatively extremely thin tube wall of the present invention. The disclosure of Hines also does not teach, or make obvious, the extremely thin walled, foil like, pleatable tube of the present invention. Several inventive, non-obvious, steps were necessary to convert the process and method used to make the typical coronary stent disclosed by Hines into an invention capable of producing the aneurysm/defect covering tube of the present invention. Please see above Points 17 and 21 for discussion of the useful and novel physical characteristics of the present invention as compared to those disclosed by Boussignac.

New Claims

New Claim 33, reciting the application of a porous surface layer to a pleated stent of Claim 1, has been added to claim with more specificity material thoroughly disclosed by the specification (at least par. 49). The technique of forming a porous layer described by applicants' granted patent, US 6,904,658, would be the preferred method for creating an eluting layer on a micro-pleated stent but any other desirable method could be used. Typical coronary stents used for drug elution are balloon expanded but not pleated, and thus they necessarily have a relatively small surface area to contact the artery for elution of a drug or other substance (par. 49).

Conclusion

Prototypes of the present invention have been produced and rigorously tested on the bench and have been deployed to successfully treat aneurysms in the brains of pigs (Exhibit A). Some of these animal studies were carried out on a humanitarian basis free of charge, by Dr. Fernando Vinuella (see Exhibit A) who is one of the most successful neurointerventionalists in the world. No cited prior art is designed for or intended for neurovascular use. No cited prior art EVER MENTIONNS neurovascular use. No cited prior art is analogous art. All cited references are out of date in this rapidly changing field and if it had been obvious or even possible to modify or combine existing art to create a workable neurovascular aneurysm stent, given the felt need to have a better solution than coiling or open surgery, such a device would have been

proposed and developed. Applicant has done what no one else could (Exhibits A and B). Dr. Vinuella developed coiling, the only non-surgical aneurysm treatment currently approved by the FDA. Applicant has received consistent advice related to the pleated stent design and development, from Dr. Vinuella and several other neuroradiologists, as well as from several neurosurgeons. Completely functioning, actual scale delivery assemblies of the present invention have been physically operated and critically evaluated by physicians and other experts in the field. The invention uses novel structure, material properties, and design, to achieve unprecedented and encouraging results in the treatment of lumen defects (Exhibits A and B).

Based upon the foregoing, applicant believes that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned. Applicant would appreciate any suggestions on amending the claims to advance the application to allowance. Applicant looks forward to working with examiner to effectively claim the patentable material and physical features of this disclosure.

Respectfully submitted,

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Date: May 2, 2008

Exhibits:

All Exhibits are contained on enclosed CD with these titles.

Exhibit A:

Successful Aneurysm treatment with applicants' pleated stent of this invention at UCLA Medical Center.

1. One slide showing pre-deployment, deployment, and immediately post deployment.
2. Stent before Carotid Siphon Photo
3. Stent around Carotid Siphon Photo
4. After Deployment Photo
5. Dr. Vinuella
6. Pig and brain on screen
7. Pre-placement video of aneurysm with blood circulating.
8. Video immediately after placement flow into the aneurysm is significantly reduced.
9. Video fourteen days after stent placement, aneurysm is cured.

Exhibit B:

Pleated stent vs. typical balloon expandable stent photographs.

1. Pleated Stent on balloon
2. Aneurysm and Coronary Stent as Manufactured
3. Pleated Stent on mandrel
4. Platinum Pleated Stents
5. Expanded Pleated Stents
6. Pleated Stent Expanded by Balloon
7. Pattern Option